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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,476	03/19/2004	Darrell Orvin Wagner	GUID.628PA	7258
51294 7590 05/22/2007 HOLLINGSWORTH & FUNK, LLC 8009 34TH AVE S. SUITE 125 MINNEAPOLIS, MN 55425			EXAMINER BERTRAM, ERIC D	
			ART UNIT 3766	PAPER NUMBER
			MAIL DATE 05/22/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/804,476

Applicant(s)

WAGNER ET AL.

Examiner

Eric D. Bertram

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 3/12/2007 have been fully considered but they are not persuasive. The applicant argues initially that neither Weiss nor KenKnight disclose the use of surface electrodes. However, as admitted by the applicant, Weiss discloses an electrode for attaching to the heart wall, which inherently has a surface. Therefore, the electrodes of Weiss are inherently "surface electrodes." Furthermore, as admitted by the applicant, KenKnight discloses positioning electrodes on the thorax of the patient. The thorax of the patient also inherently has a surface, and therefore, the electrodes of KenKnight are also inherently "surface electrodes." Furthermore, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the surface electrodes referred to in the claims does not refer to implanted electrodes) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). One of ordinary skill in the art would acknowledge that there are a plurality of surfaces both inside and outside the body. Indeed, KenKnight specifically discloses that the electrode used is attached in the ventral surface of the chest (see Col. 2, lines 38-44). Therefore, without further limitation in the claims, one would conclude that a "surface electrode" is merely any electrode that contacts a surface, given its broadest reasonable interpretation. As examples, US Patent 5,718,145 refers to a surface electrode as one that contacts the

larynx (see title), US Patent 6,240,307 refers to a surface electrode 24 that contacts the inner endocardial surface of the heart, and US Patent 6,219,581 discusses a surface electrode 30 that contacts the epicardial surface of the heart (see figure 3).

2. Regarding the applicant's arguments that multiple claims recite determining a subcutaneous location based on a surface locations, it is never recited that these positions are different. The surface locations could be referring to subcutaneous surfaces. As described in the previous Office Action and below, KenKnight discloses that the electrodes "are positioned on the thorax of the patient" while also being implanted under the surface of the skin (col. 2, lines 39-48). In other words, once implanted, the electrodes are both "on a thorax" and subcutaneous. As a result, the 35 USC 103(a) rejections of claims 1-8, 11-15, 18-24, 27, 34-36, 41, 44, 45, 48, 50 and 53-58 are still considered proper.

3. Regarding the arguments about the obviousness-type double patenting rejection in view of US Patent 7,047,071, the claims in the current application refer to rejecting subcutaneous electrode locations based on placing electrodes at a location and testing the surface pacing level of that location. The claims of US Patent 7,047,071 deal with rejecting a patient as a candidate for implantation based on placing electrodes at a location and testing the surface pacing level of that location. If after testing a location, a patient was rejected as a candidate, the location was inherently rejected as well. The double patenting rejection is still considered proper.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-60 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-57 of U.S. Patent No. 7,047,071.

Although the conflicting claims are not identical, they are not patentably distinct from each other because if all of the surface electrode locations were rejected using the method of the current application, then a subject would inherently not be suitable to receive a subcutaneous defibrillation device, as described in the patent. In other words, the same invention is being described, albeit in different terms, in both the current application and the patent.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-8, 11-15, 18-24, 27, 34-36, 41, 44, 45, 48, 50 and 53-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss in view of KenKnight (US 6,148,230). Weiss discloses an electrode placement method utilizing a plurality of electrodes 38 and 50 attached in a fixed geometrical relationship to a support structure 33, wherein the electrodes are connected to a pulse generator (col. 3, lines 63-67, col. 5, lines 1-2 and col. 8, lines 20-24). The electrodes are placed at various locations on the surface of the heart and patient threshold is tested at each location in order to find a

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desired stimulating location (col. 5, lines 3-6). As a result, multiple locations may be probed and rejected until an electrode location is selected. The testing of a patient threshold inherently relates to determining the minimum pacing level required to capture the heart. Therefore, a desired stimulating location will have a minimum pacing level that meets predetermined requirements. Once this location is found, the lead is affixed at the subcutaneous location on the heart (col. 5, lines 6-12). However, Weiss does not disclose utilizing electrodes that are placed on a thorax of a patient which relate to subcutaneous electrode locations.

10. Attention is directed to the secondary reference of KenKnight, which discloses a plurality of electrodes 22, 24, 26 all located on a support structure 20 for the purpose of pacing a heart (col. 2, lines 33-38). KenKnight discloses that the electrodes "are positioned on the thorax of the patient" while also being implanted under the surface of the skin (col. 2, lines 39-48). In other words, once implanted, the electrodes are both "on a thorax" and subcutaneous. Therefore, if the method of Weiss was carried out using the electrode positions and teaching of KenKnight, once a desired pacing location was found, it would inherently correspond to an acceptable subcutaneous electrode location. Furthermore, KenKnight is silent as to how the exact locations of the electrodes are determined. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to use the electrode placement method of Weiss with the electrodes and locations as taught by KenKnight in order to find the locations that allow the lowest pacing levels possible, which helps to decrease

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both the pain felt by the patient and the drain that occurs on the battery with each pacing pulse.

11. Regarding claims 8 and 41, the two electrodes of Weiss are considered to be an array.

12. Regarding claims 11, 12, 22, 23 and 35, the support structure 33 is also considered a housing, and when the electrodes are implanted at a selected location, the structure is inherently implanted as well.

13. Regarding claims 13 and 14, if all of the locations are rejected, then a patient is inherently not suitable to receive a subcutaneous cardiac stimulation system.

14. Regarding claims 15, 24, 55 and 57, the electrodes will inherently be placed in relation to various parts of the heart.

15. Regarding claims 53 and 56, Weiss discloses rotating the electrode 50 relative to the electrode 38 (see figure 5).

Allowable Subject Matter

16. Claims 9, 10, 16, 17, 25, 26, 28-33, 37-40, 42, 43, 46, 47, 49, 51, 52, 59 and 60 would be allowable if a timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) were filed to overcome the nonstatutory obviousness-type double patenting rejection¹ set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

17. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday from 8:30-7 EST.

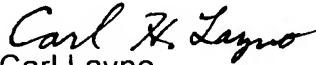
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric D. Bertram
Examiner
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